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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,059	12/29/2000	James R. Baker JR.	UM-04491	8985
23535	7590	04/01/2005	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,059

Applicant(s)

BAKER ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-87,89-99,101-104,110,111,113,114,121 and 131-133 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-87,89-99,101-104,110,111,113,114,121 and 131-133 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02/03/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of IDS, amendment and remarks filed 02/03/05. Claims 71-87, 89-99, 101-104, 110, 111, 113, 114, 121 and 131-133 are pending.

The amended claims now recite phosphate-based solvent and the phosphate-based solvent in claim 89 comprises tributyl phosphate. However, Little-van den Hurk discloses an emulsion that contains phosphate buffered saline and phosphate buffered saline is a phosphate based solvent. Secondly, Baker Jr. et al. (US 6,015,832) discloses a composition that comprises halogen containing compound, sodium hypochlorite, and phosphate-based solvent. The generic claim does not specify the halogen containing compounds and hypochlorite is a halogen-containing compound. Thus, upon reconsideration of the prior art and applicants' amendment, the finality of the rejection of the last Office action is therefore is withdrawn. The Baker reference would have been overcome if the generic claims recited the halogen containing compounds defined in claims 85 and 98 since those halogen containing compounds in claims 85 and 98 are not sodium hypochlorite.

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 71-74, 78, 79, 81-83, 89, 93-95, 104, 110, 111, 113 and 114 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker, Jr. et al. (US 6,015,832, previously cited).

Baker discloses methods of inactivating bacterial spores where the method comprises contacting the bacteria or bacteria containing surfaces and objects with an oil-in-water emulsion composition; the oil-in-water emulsion composition comprises a surfactant such as sodium

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dodecyl sulfate, organic phosphate based solvent such as tri-n-butyl phosphate, carrier oil and oligopeptides (abstract, column 2, lines 14-47, column 3, lines 5-15). The oils used are water immiscible oils such as squalene oil, fish oils, canola oil, rapeseed oil, corn oil and flavor oils (column 2, lines 53-57); the surfactants are TWEEN, TRITON, which is a pheoxypolyethoxyethanol (column 3, lines 1-4); Baker's formulation may also contain alcoholic solvent (column 3, lines 13-15). Baker also discloses method of treating a subject by applying pharmaceutically suitable bacteria inactivating composition topically to skin surfaces, mucous membranes, oral surfaces and to wounds and the composition will typically be a cream, gel, spray or mouthwash (column 3, lines 21-29). Furthermore, Baker discloses that the emulsion composition can be used to inactivate bacterial spores by topical application of the emulsion to skin or mucous membranes (column 3, lines 29-39) and can be used to inactivate bacteria and bacterial spores on surfaces that come in contact with the human and vehicles and instruments are examples of surfaces that can be decontaminated (column 3, lines 40-49). While Baker discloses evaluating the efficacy of the composition on bacterial spores by biological assay, and although Baker discloses adding sterile saline to either the culture or the emulsion (column 9, lines 3-25 and column 10, lines 23-53), Baker fails to classify the process as modifying the emulsion and it is respectfully submitted the process modifies the composition in preparation for analysis. Baker meets the limitations of the claims.

3. Claims 71-74, 76-78, 80-87, 90-95, 97-99, 101-104, 113 and 114 are rejected under 35 U.S.C. 102(b) as being anticipated by Spitzer et al. (US 3,912,666).

Spitzer discloses oil-in-water emulsion (abstract, column 6, line 34) that contains halogen compound such as vinyl chloride, methyl chloride, propellants and Freon and halogenated

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solvents (column 6, line 66 to column 7 line 9; column 8, lines 57-64), oil phase and aqueous phase (column 9, lines 31-42), surfactant such as sodium dodecyl sulfate, polyethylene glycol esters, cetyltrimethylammonium bromide (column 10, lines 16-67), ethyl alcohol or methyl alcohol or isopropyl alcohol or glycerol (column 11, lines 15-19). Spitzer's formulation may contain plasticizers such as tricresyl phosphate, butyl glycolate, citrate, phthalate (column 9, line 1-5). Cetyltrimethylammonium bromide is also a halogen-containing compound, of the type applicants regard as halogen-containing compound, that has deodorizing and antiseptic properties (column 12, lines 18 and 19). Spitzer discloses that the oil-in-water emulsion composition is topically applied as cleansing, conditioning, coating, lubricating agents, personal washing, laundering, dishwashing, shampoos, shaving cream, hair color and rinses (column 12, line 58 to column 13 line 13); Spitzer's oil-in-water emulsion composition is also useful as furniture and shoe cleaners and polish (column 13, lines 14-20). Spitzer's oil-in-water emulsion composition may also contain medicaments such as antimicrobial agents (column 13, lines 22-61). Regarding medical device, applicants' specification in paragraph [0091] of the published application defines medical device as a "drug delivery devices" and Spitzer incorporates medicaments such as histamines, sulfa drugs, antibiotics, hormones, vitamins, antimicrobials agents and procaine (column 13, lines 22-53). See also Examples 1-2. The aqueous phase in Spitzer is about 10% to about 75% by weight of the emulsion and by corollary (claim 17), the oil phase would be from about 90% to about 25% by weight of the emulsion and since the density of the emulsion would not be drastically different than the density of water at 1, the weight percent would approximate volume percent. Spitzer meets the limitations of the claims.

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4. Claims 71-74, 78-87, 90, 92-95, 97-99, 101-104, 113 and 114 are rejected under 35 U.S.C. 102(e) as being anticipated by Little-van den Hurk et al. (US 5,951,988, previously cited).

Little-van den Hurk discloses oil-in-water emulsion that contains halogen containing compound (column 2, lines 12-56), oil selected from the group consisting of mineral oils, vegetable oils and animal oils (column 2, lines 58 and 59; column 4, lines 29-54), ethanol (column 4, line 60), sodium lauryl sulfate (column 5, lines 2-14), phosphate buffered saline (column 5, line 19), and the emulsion may contain TWEEN (example 1). The vegetable oils include canola oil, almond oil, cottonseed oil, corn oil, olive oil, peanut oil, safflower oil and sesame oil (column 4, lines 52-54). The oil-in-water emulsion composition is administered to animals and a measure of the immune response is assayed (Example 2). The formulation of Little-van den Hurk contains lower alcohols such as ethanol, isopropanol and butanol (column 4, lines 59 and 60) and natural emulsifiers such lecithin may be employed (column 5, lines 13 and 14) and lecithin is a germination enhancer. The teachings of Little-van den Hurk meet the limitations of the claims.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 75 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (US 6,015,832).

Baker discloses the instant antimicrobial composition. Baker does not disclose that the emulsion has motor oil. However, one oil type may be used in place of another oil type. There is no demonstration that the motor oil provides unusual results. Thus, it would have been

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obvious to one of ordinary skill in the art at the time the invention was made to prepare the emulsion of Baker. One having ordinary skill in the art would have been motivated to substitute one oil type for another with the expectation that the oil-in-water emulsion would provide the desired function as an anti-microbial.

7. Claims 121 and 131-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (US 6,015,832).

Baker is discussed under 35 USC 102. Baker also discloses that the emulsion is used to inactivate bacteria and bacterial spores on surfaces that come in contact with humans (column 3, lines 40-45). Furthermore, Baker indicates that the emulsions may be combined with edible substances for swallowing (column 5, lines 33-45). Since the emulsion is capable of inactivating bacteria or bacterial spores on any surface that it comes in contact with, it stands to reason, the emulsion may also do the same when it is in contact with edible substance. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use bakers composition to inactivate surfaces that come in contact with human. Since food comes in contact with humans, combining the emulsion with edible substance would inactivate bacteria present in the edible substance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center

A handwritten signature in black ink, appearing to read 'Blessing Fubara', is written over the printed name.